REMARKS

Claims 1-2, 7-18 and 20-21 are pending in this application. None of the claims have been allowed.

At page 2, paragraph 1 of the Office Action the Examiner states:

> "Applicant's election **without** traverse of the species **pergolide** as the first antiparkinson agent, **selegiline** as the second antiparkinson agent, and **VIOXX®** as the COX-2 inhibitor, in the reply filed 1/22/2008 is acknowledged.
>
> Claims 4-6 and 9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Additionally, claim 3 has been canceled. Accordingly, claims 1-2, 7-8 and 10-21 are examined on the merits herein in so much as they read on the elected species."

In response, Applicants have cancelled claims 4-6. [As noted by the Examiner, claim 3 was previously cancelled.] Applicants respectfully suggest that the Examiner's withdraw of claim 9 is in error. Claim 9 states: "A method according to claim 2 wherein the monoamine oxidase agent comprises selegiline."

At page 3, paragraph 4 of the Office Action, the Examiner states:

> "The use of the trademark VIOXX® has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.
>
> Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks."

In response, Applicants have amended the specification as indicated.

At page 3, paragraph 5 of the Office Action, the Examiner states:

> "Claims 1-2, 7-8, and 10-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for **treating** Parkinson's disease and relieving the symptoms of Parkinson's disease, does not reasonably provide enablement for the **prevention** of

> the Parkinson's disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims."

Applicants respectfully traverse. With the exception of claim 19, none of the claims are directed toward prevention. The claims are, for example, directed to treatment; slowing the progress; and ameliorating symptoms. Accordingly, applicants respectfully request withdrawl of the rejection with regard to claims 1-2, 7-8, 10-18, and 20-21. While applicants disagree that claim 19 is not enabled, they have nonetheless cancelled claim 19 in order to advance the prosecution of the application. Applicants specifically reserve the right to prosecute cancelled and un-claimed subject matter in a continuing or divisional application.

At page 8, paragraph 6 of the Office Action, the Examiner states:

> "Claims 1-2, 7-8, and 10-21 contain the trademark/trade name VIOXX® (as these claims read on the elected species). Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe rofecoxib and, accordingly, the identification/description is indefinite."

In response, Applicants have amended the claims a requested.

At page 10, paragraph 8 of the Office Action, the Examiner states:

> "Claim 18 is rejected under 35 U.S.C.103 (a) as being unpatentable over Block et al. (WO 00/27382).
>
> The instant claim 18 is directed to methods of slowing the progress of Parkinson's disease and preventing Parkinson's disease comprising administration to a patient in need thereof a therapeutically effective

amount of the selective COX-2 inhibitor VIOXX® (rofecoxib). The prior art is applied to these claims in so much as they read on methods of **treating** Parkinson's disease.

Block et al. teaches the administration of a therapeutically effective amount of a combination of $GABA_A$ alpha 5 inverse agonist and COX-2 inhibitor for treating neurodegenerative conditions such as Parkinson's disease (see abstract, page 1, lines 27-30, and page 22, lines 10-16). Block et al. further teached that the COX-2 inhibitor is preferably rofecoxib (VIOXX® (see page 33, lines 17-18).

Block et al. does not explicitly teach a method of treating Parkinson's disease comprising the administration to a patient in need thereof a therapeutically effective rofecoxib.

However, it would have been obvious to one of ordinary skill in art at the time of the invention, to treat Parkinson's disease in a patient comprising the administration to said patient a therapeutically effective rofecoxib using the guidance of Block et al. One ordinary skill in the art would have a reasonable expectation of success in doing so because the prior art as a whole teaches treating Parkinson's disease with rofecoxib. Thus, the invention would have been *prima facie* obvious to one skilled in the art at the time it was made."

At page 11, paragraph 9 of the Office Action, the Examiner states:

"Claims 1-2, 7-8, 10-17, and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Block et al. (WO 00/27382) as applied to claim 18 in view of Shapiro (US 5,668,117).

Claims 1-2, 7-8, 10-17, and 20-21 are directed to methods of treating Parkinson's disease, relieving the symptoms of Parkinson's disease and/or ameliorating/slowing the progress of Parkinson's disease comprising administration of a therapeutically effective amount of pergolide, and rofecoxib, and in claims 10 and 21, additionally selegiline. The prior art is applied to these claims in so much as they read on methods of **treating** Parkinson's disease and its symptoms.

Block et al. is described *supro* as applied to claims 16-18.

Shapiro teaches known antiparkinson agents used in the treatment of Parkinson's disease, such as pergolide mesylate and selegiline (see columns 28-30, lines 30-25) in combination with a carbonyl trapping agent in the clinical treatment of Parkinson's disease (see abstract).

> Shapiro et al. does not teach COX-2 inhibitors such as VIOXX® (rofecoxib) in the treatment of Parkinson's disease.
>
> However, it would have been obvious to one of ordinary skill in the art to treat Parkinson's disease by administering therapeutically effective amounts of (1) rofecoxib as taught by Block et al. in combination with (2) pergolide and/or (3) selegiline as taught by Shapiro."

At page 12, paragraph 9 of the Office Action, the Examiner continues:

> "In regards to the instant claims 11 and 17, that claim methods of treating the different stages/types of Parkinson's disease, it is presumed that the above components (rofecoxib, pergolide, and selegiline) taught by the prior art, treat all stages and types of Parkinson's disease absence evidence to the contrary."

Applicants respectfully traverse and direct the Examiner to Example 1 at page 15 of the application. As seen, prior to treatment, Patient 1 scored a 20 in the UPDRS test. The patent was then treated with pergolide (0.25mg tid) and selegiline (5mg po). After 6 months on this treatment regime the patients USDRS score was reduced to 16.5. After 3 additional months, VIOXX (25mg, once a day) was added to the treatment regime, and after 4 additional months on the tripartite regime the patients USDRS was a stunning 6.0. After 6 additional months one this tripartite regime, the patients USDRS was 4.0.

Applicants respectfully submit that these data demonstrate the dramatic and surprising superiority of the invention. For completeness on this issue, Applicants have ordered a copy of the Fahn, et. al. reference mentioned in Example 1 and will submit a copy of the reference in an IDS.

Having addressed the outstanding issues, Applicants respectfully request early examination and allowance of the claims. The Examiner is invited to contact the undersigned attorney at the telephone number provided below if such would advance the prosecution of this application.

Respectfully submitted,

By _____

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